MAR 1 3 2014

510(k) Summary : K133097

2.1. SUMMARY OF SAFETY AND EFFECTIVENESS

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J2L 2N8
Date Prepared: March 13th, 2014

2.2. Trade/Proprietary Name: E-Z-Link

2.3. Common/Usual Name: Vial Adapter/Reconstitution Device

2.4. Classification Name: Intravascular Administration Set
Regulation Number: 21CFR 880.5440
Class : II
Product Code: LHI

2.5. Device description:

The E-Z-Link device is a sterile, single use device that, through the use of a stainless steel cannula (needle), facilitates creation of a sterile fluid path to transfer liquid from a standard luer lock syringe to a standard pharmaceutical 13 mm vial containing a drug, in order to mix or reconstitute the drug and aspirate and transfer the prepared drug back into the luer lock syringe for delivery. The product line will include devices with different gauge transfer needles (20 and 27 Gauge).

2.6. Statement of intended use

The device is a sterile, single use device indicated for the preparation of drugs in a standard vial using liquid from a standard luer lock syringe and transfer of the prepared drug back into the syringe for delivery.

The device is intended to be used by health care professionals (HCPs) such as nurses and pharmacists in a clinical setting.

2.7. Substantial Equivalence

The E-Z-Link device is substantially equivalent to the Smart-Rod (K070584) and the Clip'n'ject (K041691).

2.8. Technological Characteristics

The E-Z-Link shares the same and does not introduce any new technological characteristics as the predicate devices. The device characteristics are as follows:

- Manually operated
  - Device is manually, mechanically connected to a compatible drug vial
  - Liquid is manually transferred using a syringe plunger rod
  - Mixing is manually achieved through manual agitation of the vial
  - Liquid is manually aspirated using a syringe plunger rod
- Terminally sterilized and provided sterile
- For single use only
- Penetrates the vial stopper with a stainless steel or a plastic cannula
- Assembled from plastic injection molded and/or stainless steel components
- has a sterile, biocompatible fluid path

2.9. Performance Data

Data on the following testing were generated verifying the design of the device:

- Needle patency
- Leak Testing of connections per ISO 594-1.
- Needle Attachment Force per ISO 7864:1993(E)
- Transfer Holdup Volume
- Force to transfer liquid to vial
- Vial attachment force
- Vial Detachment force
- Packaging Removal Force
- Force to Attach/Detach luer lock syringe
- Needle Shield Override force
- Coring/Fragmentation
- Biocompatibility: per ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

2.10. Conclusion

Based on the information presented, Duoject Medical Systems concludes that the new product is substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2014

Duoject Medical Systems Inc.
Marie-Christine Messier
Quality Manager
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Bromont, Quebec J2L 2N8

Re: K133097
Trade/Device Name: E-Z Link
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: February 6, 2014
Received: February 12, 2014

Dear Ms. Messier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

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Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K133097

Device Name

E-Z-Link

Indications for Use *(Describe)*

Single use, sterile device for preparation of drugs in a standard vial using liquid from a standard luer syringe to transfer the prepared drug back into the syringe for delivery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman
Date: 2014.03.12
17:12:12 -04'00'

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